510(k) Summary of Safety and Effectiveness:

TYBER MEDICAL Interbody System

Submitter by:	Tyber Medical LLC 89 Headquarters Plaza North, #1464 Morristown, New Jersey 07960
Contact Person	Jeff Tyber CEO and President Phone: (303) 717-5060 Fax: (866) 889-9914 Email: jtyber@tybermed.com
Date Prepared	December 17, 2013
Common Names	Bone Compression Screw
Trade Name	Tyber Medical Trauma Screw
Classification Name and Number	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Product Code	HWC
Predicate Devices	1. WRIGHT COMPRESSION SCREWS; Wright Medical – K082320 2. HEADLESS COMPRESSION SCREW; Synthes – K021556 3. VILEX/DUAL CANNULATED BONE SCREW; Vilex – K973309
Device Description	General trauma screw for compression and fixation of bone. The sterile and non-sterile implants come solid and cannulated, titanium and stainless steel.
Intended Use/ Indications for use	A trauma screw designed to apply compression and fixation between two adjacent segments of cortical and/or calcaneus bone. The Tyber Medical Trauma Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.
Performance Data (Non-Clinical and/or Clinical)	Non-clinical mechanical testing was performed consisting of Pullout and Torsional Yield per ASTM F564. All data indicates the device is substantial equivalence to the predicate systems Clinical data and conclusions were not needed for this device.
Statement of Technological Comparison	The Tyber Medical Trauma Screw and its predicate devices have the same indications for use; same design; are made of similar materials, same application, and have the same anatomic mechanical properties.
Conclusion	The Tyber Medical Trauma Screw is substantially equivalent to its predicate devices. This conclusion is based upon indications for use, materials, design, test data and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2014

Tyber Medical LLC
Mr. Jeff Tyber
President and CEO
89 Headquarters Plaza North, #1464
Morristown, New Jersey 07960

Re: K133842
Trade/Device Name: Tyber Medical Trauma Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 18, 2013
Received: December 23, 2014

Dear Mr. Tyber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133842 (pg 1/1)

Device Name: Tyber Medical Trauma Screw

Indications for Use:

The Tyber Medical Trauma Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

Prescription Use X **AND/OR** **Over-the-counter** _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Frank -S

Division of Orthopedic Devices